

## REMARKS

Entry of the amendments is respectfully requested. Claims 19, 30, and 42 have been have been amended. Claims 40-41 have been canceled. Claims 1-39 and 42-44 are pending in the application. Favorable reconsideration and allowance of this application is respectfully requested in light of the foregoing amendments and the remarks that follow.

### 1. Objection to the Amendments to the Specification

The Amendments to the Specification filed on January 8, 2007 are objected to because they allegedly add new subject matter into the disclosure. The Examiner contends that replacing Figure 1 with Figures 1-A and 1B is not supported by the original disclosure. In the Response to Arguments Section of the Office Action, the Examiner states (emphasis added) that "The declaration clearly shows that the figure 1B pertains to an entirely new analysis of data not present in the as-filed specification. Therefore, the material added constitutes the addition of new data to the specification." However, as was explained in the Response filed on January 8, 2007 and supported by the Rehberger Declaration, the Examiner found Figure 1 to be illegible. To address this problem, replacement Figures 1A and 1B were submitted. Replacement Figure 1A is a digital image of original photograph shown in Figure 1. (Previously submitted Rehberger Declaration ¶3). Replacement Figure 1B was created by taking the digital image of Figure 1A and analyzing it with a software program (BioNumerics, Applied Maths, Belgium) used for analysis of DNA banding patterns. The software program marks each band on the gel with a mark which collectively is the fingerprint for each enzyme used in the pulse field electrophoresis gel of Figure 1A. (*Id.*, ¶3).

Because Figure 1A is a digital image of original Figure 1, and Figure 1B is an analysis of Figure 1A, the replacement figures are supported by the original disclosure. Therefore, withdrawal of the objection is requested.

### 2. Rejection Under §112, First Paragraph

Claims 19-35 and 40-41 stand rejected under 35 U.S.C. §112, ¶1, as failing to meet the written description requirement. The Examiner states that "Applicant has not indicated the correction of an error in the original figure, but rather a further analysis of the data, which was not in possession of applicant at the time the claimed invention was made, as evidenced by the

instant written disclosure." Although an error per se was not earlier identified, it was pointed out that the replacement drawings were to address a legibility problem with original Figure 1.

Furthermore, all of the figures are related: Figure 1A is a digital image of Figure 1, and Figure 1B is a further analysis of Figure 1A. Brand new drawings not based on originally submitted drawings were not submitted. Instead, Figures 1A and 1B, which are supported by the originally submitted disclosure, were submitted to show that the inventors had possession of the claimed invention as of the filing date of the instant application. The replacement figures do so because they are based on Figure 1. Claims 40-41 have been canceled, obviating the rejection of these claims.

In light of the foregoing arguments, withdrawal of this rejection is requested.

### 3. Rejection Under §112, Second Paragraph

Claims 19-35 and 40-41 stand rejected under 35 U.S.C. §112, ¶2 as being indefinite.

Claim 19 is rejected due to the recitation of "a Profile I" Claim 19 and 30 has been amended to replace "a Profile I" with "*the* Profile I." Applicants previously used "a Profile I" to provide antecedent basis for the term Profile I, not to make the claim read on various "Profile I" variants. In light of the amendment to claims 19 and 30, withdrawal of this rejection is requested.

The Office Action also states that due to issues with the new Figures, "the strains encompassed by the claim designated language cannot be reliably identified." However, the Examiner has not identified what the issues are, nor has she identified the claims to which this concern pertains. In light of this, withdrawal of this rejection is requested.

The Examiner states "Table 6 provides strain designations and species designations, but the correlation with Profile I is unclear. The Figure and Table are not informative regarding the specific properties of the strains intended to be claimed." Applicants contend that the specific properties are the DNA profiles shown in the figures and referenced in Table 6. The previously filed response and the specification explain the various DNA profiles that were obtained. Therefore, the correlation should be clear. Furthermore, the Examiner has not identified the claims to which this concern pertains. In light of these facts, withdrawal of this rejection is requested.

The Examiner states "The reasons or criteria for designating pigs as "*representative*" for

inclusion in Table 6 data are not set forth with any particularity on the record." However, applicants clearly stated in the January 8, 2007 Response that "in Table 6, the term "representative pigs" was used because it was a subset of the pigs that were examined. That is, less than all pigs were used, and no specific reason for including one, but not another pig, was used. Support for this statement was provided in ¶6 of the Declaration of co-inventor Dr. Thomas Rehberger. In light of these facts, withdrawal of this rejection is requested.

Claim 26 is again rejected due to the recitation of "milk replacer." This rejection is respectfully traversed because this term is well understood by those skilled in the art, as shown by the evidence previously supplied. The MPEP states that "The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." MPEP §2173.02. In the January 8, 2007 Response, Applicants supplied evidence that milk replacer is well known by those skilled in the art by providing a list of 162 U.S. patents, each of which uses milk replacer, and of which twenty-five use this term in the claims (attached as Exhibit A to January 8, 2007 Response). The term milk replacer complies with the definiteness requirement because those skilled in the art and those patenting inventions in this art are using this term. Furthermore, the USPTO is granting patents including this term even when it is used in the claims of patents.

Applicants fail to understand how the Examiner's argument that milk can be replaced by water or any other liquid negates this evidence. In fact, milk can be replaced by water, and Claim 27 actually requires the milk replacer to be water. Moreover, the Examiner has not indicated that she is one possessing the ordinary level of skill in the pertinent art at the time the invention was made, as the MPEP requires of those interpreting the claims containing this term. As such, the rejection is improper and must be withdrawn.

Claims 40-41 have been canceled, obviating the rejection of these claims.

In light of the arguments presented, withdrawal of the rejection is requested.

#### 4. Rejections Based on the Prior Art

Claims 19-28, 30-35, and 40 stand rejected under § 102(b) as being anticipated by and/or under § 103(a) as being unpatentable over Tannock et al., Krause et al, Benoit et al., Coventry et al, Schutz, Lewus et al, Craig et al. (U.S. Patent No. 5,795,602), and Iritani et al. (U.S. Patent No. 6,090,416), either alone or in combination. The applicants respectfully traverse this

rejection because, as is discussed below, the references, alone or in combination, do not disclose each and every element of the claimed invention, nor do they teach or suggest the claimed invention. Therefore, reconsideration is in order and is respectfully requested.

a. Anticipation Rejections

It is well settled that the examiner must carry the initial burden of establishing a *prima facie* case of anticipation by showing that all of the claimed elements of the claimed invention are described in a single reference sufficiently to have placed a person of ordinary skill in the art in possession of it. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *Spada*, 911 F.2d at 709, 15 USPQ2d at 1658 (emphasis added).

The Examiner has taken the position that one or more of the cited references inherently anticipates the rejected claims. However, inherency is not a sometime thing. "The law requires that inherency may not be established by possibilities or probabilities. The evidence must show that the inherency is necessary and inevitable." *Interchemical Corp. v. Watson*, 111 USPQ 78, 79(d) (D.C. 1956), *aff'd*, 116 USPQ 119 (D.C. Cir. 1958); MPEP §2112.

Claims 19 and 30 require a *Lactobacillus* strain that has the Profile I based on *Apa* I, *Not* I and *Xba* I digests. The instant specification, e.g. at Table 6, clearly shows that seven different profiles were identified in the *Lactobacillus* strains isolated by the inventors. The specification further shows that a single *Lactobacillus* species can have one (or another) of these seven different profiles. Also, a *Lactobacillus* strain having a specific profile can be of different species. Thus, it is clear from evidence in the specification that there is both variability and unpredictability in the profile that a strain possesses.

Furthermore, it is not bald argument of counsel that is relied to show that the cited references do not disclose strains having the Profile I that is required by the rejected claims. Instead, it is the evidence of record that shows that the *Lactobacillus* strains shown in these references do not necessarily have the Profile I that is required by the rejected claims. There is no other evidence in the record that establishes the contrary. The Examiner's showing in the cited references of *Lactobacillus* strains isolated from a pig does not meet the legal standard of necessity and inevitability where the strain could have one of seven or more profiles.

Accordingly, on the record, the examiner has not made out a *prima facie* case of anticipation by establishing a sound basis for believing that the strains listed in the claim and the prior art are the same. Thus, the burden has not shifted to the applicant to present additional evidence that they are not.

Claim 40 has been canceled, obviating the rejection of this claim.

Withdrawal of the anticipation based rejections is respectfully requested.

b. Obviousness Rejections

The examiner also has the initial burden of establishing a *prima facie* case of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP § 2142. The Applicants believe that the Examiner has failed to make a *prima facie* case of obviousness, and, more particularly, has failed to establish the inherency of undisclosed properties. Specifically, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03 (citing to *In re Royka*, 180 USPQ 580 (CCPA 1974)). Here, the microorganism recited in the claims is distinguishable from the cited reference based on identified characteristics, i.e., having the Profile I based on the restriction enzyme digests listed in claims 19 and 30. Thus, all the claim limitations are not taught or suggested by the prior art, and the references would not have made claims 19 and 30 obvious.

Furthermore, with respect to inherency, the Examiner has failed to show that the undisclosed elements must be present in the prior art reference. Inherency of an undisclosed element can only be established by showing that the inherency is necessary and inevitable and not merely possible or even probable. *Interchemical Corp. v. Watson*, 111 USPQ 78, 79(d) (D.C. 1956), *aff'd*, 116 USPQ 119 (D.C. Cir. 1958); MPEP §2112. In addition, inherency and obviousness are distinct concepts. *W.L. Gore & Assoc. v. Garlock, Inc.*, 220 USPQ 303, 314 (Fed. Cir. 1983). In order to establish a *prima facie* case of obviousness based on inherent properties, the Examiner must show that the undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art. *Kloster Speedsteel AB v. Crucible Inc.*, 230 USPQ 81, 88 (Fed. Cir. 1986). The Examiner has failed to meet this burden. As is detailed above, it is clear from evidence in the specification that there is both variability and unpredictability in the profile

that a *Lactobacillus* strain possesses. Accordingly, the combined teachings of the references would not have made claims 19 and 30 obvious or the claims that depend therefrom.

Claim 40 has been canceled, obviating the rejection of this claim.

Accordingly, withdrawal of the obviousness rejections is therefore requested.

5. Allowable Claims

No rejections are listed for claims 41-44. Therefore, applicants believe that these claims are allowable. Claim 42 has been rewritten in independent form to include all of the limitations of the base claim.

CONCLUSION


It is submitted that claims 19-39 and 42-44 are in compliance with 35 U.S.C. §§ 112, 102, and 103 and each define patentable subject matter. A Notice of Allowance is therefore respectfully requested.

The Director is authorized to charge Deposit Account No. 23-2053 for the fee associated with a one (1)-month extension, which the Applicants hereby request. No other fee is believed to be payable with this communication. Nevertheless, should the Examiner consider any other fees to be payable in conjunction with this or any future communication, the Director is authorized to direct payment of such fees, or credit any overpayment, to Deposit Account No. 23-2053.

The Examiner is invited to contact the undersigned by telephone if it would help expedite matters.

Dated this 22nd day of June, 2007.

Respectfully submitted,

  
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